R&D Taskforce position paper: One Stop Shop & Clinical Trials Front Door

December 2021

A. Summary of recommendations

The R&D Taskforce (RDTF) strongly supports the focus and investment in a One Stop Shop and National Clinical Trials Front Door as a significant step forward in making the necessary improvements to increase Australia's global competitiveness in clinical trials.

The primary objectives of the One Stop Shop and Front Door should be to ensure the Australian clinical research environment is efficient, cost-effective and operates to world's best practice now and in the long-term. To achieve this, the following principles should be implemented:

1. **Efficient start up:** Clinical trials must be able to commence quickly and efficiently across many clinical trial centres around Australia.
2. **Capacity:** Australia needs to be able to connect participants with appropriate clinical trials in an efficient and timely manner.
3. **Competitiveness:** Australia must compete internationally with other countries on a cost basis.
4. **Continuous review:** To remain competitive over time, the One-Stop Shop and the Front Door will need to be continually reviewed against the needs of the clinical trials sector and the changing international environment.

B. The value of clinical trials in Australia

Clinical trials provide benefit to Australian patients, the healthcare system and the broader medical research industry. They provide a mechanism for consumers to gain early, no-cost access to innovative treatment across a broad range of diseases and contribute to better healthcare outcomes by generating evidence that drives improvements in clinical practice.

It is recognised that Australia's medical research sector makes a significant contribution to the economy. For every $1 invested in medical research in Australia, $3.90 is returned to the broader economy. In addition, the sector employs more than 32,000 people directly, with a further 78,000 in the downstream medical technologies and pharmaceuticals sector.[1]

[1] Economic Impact of Medical Research in Australia, a KPMG study commissioned by the Association of Australian Medical Research Institutes (AAMRI) October 2018.

Medicines Australia

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

MTAA Medical Technology Association of Australia

Clinical trials are a significant component of the medical research industry. Through clinical trials, hospitals receive funding for resources, such as study site personnel, academic projects and opportunities are provided to retain specialised researchers. In 2019, $1.4 billion were invested in clinical trials, with industry investment accounting for approximately 79% of this expenditure.[2] Although considered to be an underestimation, there were at least 8000 Australian jobs supported by the clinical trials sector in 2019.[3]

C. Australia's current clinical trial environment

Despite the significant health and economic benefits of Australian-based clinical trials, the clinical trials environment in Australia is not internationally competitive. Australia is less competitive than emerging and established markets on clinical trial measures of timely and efficient trial start-up, cost, and the capacity to recruit trial participants. Delivering a multi-centre trial in Australia across state and territory borders continues to involve significant duplication of effort, complexity and inconsistency in approach with variable and unreliable return on contracted participant numbers in the agreed timelines.

Since 2006, the need for clinical trial reform in Australia has been well recognised. Several committees, working groups, consultation forums and other initiatives have been implemented at Federal and State levels. Many of these have had positive and somewhat impactful outcomes, others less so. Overall, despite best intentions, progress has been slow and has not kept pace with the speed with which competing countries are developing their infrastructure and expertise.

The environment in which clinical trials are conducted in Australia is characteristically fragmented with many different organisations or health departments sharing responsibilities for certain aspects of clinical trials. These include the National Health and Medical Research Council (NHMRC), Therapeutic Goods Administration (TGA), Federal Department of Health and Ageing, and State and Territory Governments. It is important to note that as of 30th June 2017, the NHMRC ceased all activities associated with clinical trial improvement initiatives.

It is now widely recognised by governments, industry and researchers that significant improvements are needed to increase Australia's ability to attract commercial clinical trials. These improvements must ensure that the significant contribution that clinical trials make to Australian patients and the economy will continue to grow.

D. Aims of the One Stop Shop and Clinical Trials Front Door

The RDTF welcomes the investment in a One Stop Shop and National Clinical Trials Front Door as a significant step to making the necessary improvements to increase Australia's global competitiveness in clinical trials by harmonising the current fragmented environment and removing inefficiencies in processes and systems across all States and Territories.

---

[2] MTPConnect. (2021). Australia's Clinical Trials Sector: https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021

[3] Ibid.

The RDTF understands that according to the Aged Care Quality and Safety Commission (the Commission), together the One Stop Shop and Front Door will:

- include a single cross-jurisdictional ethics and governance approvals platform that incorporates key application, notification and approval systems
- incorporate the Clinical Trials Notification (CTN) and Clinical Trials Approval (CTA) schemes administered by the TGA
- include an embedded and automated national clinical trials registry
- provide sophisticated monitoring and reporting functionality for different users.
- underpin the newly developed National Clinical Trials Governance Framework and the accreditation of health services for the conduct of clinical trials

The R&D Taskforce strongly supports the Commission in developing the One Stop Shop and Clinical Trials Front Door and look forward to engaging in the consultations.

E. Industry priorities for the One Stop Shop and Clinical Trials Front Door

The primary objectives of the One Stop Shop and Front Door should be to ensure the Australian clinical research environment is efficient, cost-effective and operates to world's best practice now and in the long-term. To achieve this, the following principles should be implemented:

1. **Efficient start up:** Clinical trials must be able to commence quickly and efficiently across many clinical trial centres around Australia.
    - The approval granted by an accredited ethics committee should be mutually accepted by all clinical trial centres without exception and without additional written agreements being required.
    - A single Ethics Application via the One Stop Shop should allow collaboration during the development of the application by a sponsor and a lead investigator (where the two are not the same entity), and which allows for either party to take responsibility for the submission step.
    - A single Research Governance Application that brings consistency and speed to the process of governance at each participating institution that can be completed in parallel with the Ethics Application process.
    - Ability to submit the CTN (or CTA) to the TGA without duplication of data entry; the system could automatically fill relevant fields of the e-CTN from data field completed as part of the Ethics and Governance applications.
2. **Capacity:** Australia needs to be able to connect participants with appropriate clinical trials in an efficient and timely manner.
    a. The recruitment of participants to clinical trials is not a one-size-fits-all approach and that various strategies are required to be deployed for different types of studies.
    b. ANZCTR (current or future version) and www.AustralianClinicalTrials.gov.au website should be merged into the One Stop Shop and Front Door.

c. Patients should be able to register their interest in clinical trials via a registry.

d. Electronic Medical Records could also be integrated into the Front Door to allow for AI software to articulate the feasibility of clinical trials in Australia and help to identify geographic patterns to indicate where sites should be opened for studies.

3. **Competitiveness:** Australia must compete internationally with other countries on a cost basis. The following KPIs and metrics should be published:

   - The cost of conducting clinical trials in Australia, to ensure costs are fair and in-line with international benchmarks.
   - Granularity on Start-up timelines from Site Selection to Last Site activated.
   - Volume of clinical trials which can be split into by Phase, therapy area, location, sponsor type, etc.
   - Participant recruitment data, including actual versus planned/contracted (per the CTRA).
   - Analysis of metadata around the conduct of clinical trials.

4. **Continuous review:** To remain competitive over time, the One-Stop Shop and the Front Door will need to be continually reviewed against the needs of the clinical trials sector and the changing international environment.

F. About the R&D Taskforce

Since 2006, the RDTF has been a unique forum for developing, evaluating and providing expert advice to Government on issues affecting clinical research in Australia. Convened by Medicines Australia, AusBiotech and the Medical Technology Association of Australia, the RDTF brings together senior executives from the peak bodies and companies representing the industry sectors, including the research-based and the biotechnology sector. In addition, these sectors are among the Australian health system's most crucial components: they research, develop, manufacture and distribute supply products that Australians use to lead healthier and more productive lives.

The RDTF is committed to working with all stakeholders to ensure that our clinical research industry remains a strong contributor to this country's economy and to the health and wellbeing of all Australians.